

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of

MAERTENS et al

Atty. Ref.: 2752-45

(Divisional of Serial No. 09/638,693)

Group: Unassigned

Serial No. To be Assigned

Filed: June 5, 2001

Examiner: Unassigned

For: NEW SEQUENCES OF HEPATITIS C VIRUS GENOTYPES AND THEIR USE OF  
THERAPEUTIC AND DIAGNOSTIC AGENTS

\* \* \* \* \*

June 5, 2001

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

**PRELIMINARY AMENDMENT**

Kindly preliminarily amend the above-referenced application as follows:

**IN THE CLAIMS**

Kindly cancel claims 1-23, without prejudice.

Kindly add the following new claims:

--24. (new) An isolated polynucleic acid sequence consisting of 8 or more contiguous nucleotides selected from an HCV subtype 3c genomic sequence selected from the region spanning positions 1 to 957 of the Core of Core/E1 region of HCV subtype 3c, wherein said polynucleic acid sequence is capable of hybridizing to HCV type 3c, but not another type or subtype of HCV; or

the complement of said polynucleic acid, wherein said polynucleic acid contains at least one genotype-specific nucleotide.

25. (new) An isolated Hepatitis C virus polynucleic acid selected from the group consisting of:

- (i) the nucleotide sequence of SEQ ID NO:147,
- (ii) at least 8 contiguous nucleotides of a nucleotide sequence having at least one genotype-specific nucleotide from the region spanning positions 1 to 957 of the Core or Core/E1 region of HCV subtype 3c, and,
- (iii) the complement of the nucleotide sequence of (i) or (ii).

26. (new) A recombinant vector comprising a vector sequence and a prokaryotic, eukaryotic or viral promotor sequence operably linked to a polynucleic acid sequence of claim 24.

27. (new) A recombinant vector comprising a vector sequence and a prokaryotic, eukaryotic or viral promotor sequence operably linked to a polynucleic acid sequence of claim 25.

28. (new) A method of detecting or screening for one or more HCV genotypes present in a biological sample, comprising the following steps:

- (i) providing a sample nucleic acid,
- (ii) determining the presence of a polynucleic acid sequence according to claim 24, by means of a sequencing reaction, and,
- (iii) inferring from the presence of one or more of these HCV polynucleic acid sequences of step (ii) the genotype(s) present in said sample.

29. (new) A method of detecting or screening for one or more HCV genotypes present in a biological sample, comprising the following steps:

- (i) providing a sample nucleic acid,
- (ii) determining the presence of a polynucleic acid sequence according to

claim 25, by means of a sequencing reaction, and,

(iii) inferring from the presence of one or more of these HCV polynucleic acid sequences of step (ii) the genotype(s) present in said sample.

30. (new) A method of detecting or screening for one or more HCV genotypes present in a biological sample, comprising the following steps:

(i) providing a sample nucleic acid,  
(ii) specifically amplifying a polynucleic acid sequence according to claim 24,  
and,

(iii) inferring from the presence of one or more amplified HCV polynucleic acid sequences of step (ii) the genotype(s) present in said sample.

31. (new) A method of detecting or screening for one or more HCV genotypes present in a biological sample, comprising the following steps:

(i) providing a sample nucleic acid,  
(ii) specifically amplifying a polynucleic acid sequence according to claim 25,  
and,  
(iii) inferring from the presence of one or more amplified HCV polynucleic acid sequences of step (ii) the genotype(s) present in said sample.

32. (new) An isolated HCV polynucleic acid according to claim 24, wherein said polynucleic acid is capable of acting as a primer for specific amplification for HCV type- or subtype-specific amplification.

33. (new) An isolated HCV polynucleic acid according to claim 25, wherein said polynucleic acid is capable of acting as a primer for specific amplification for HCV type- or subtype-specific amplification.

34. (new) An isolated HCV polynucleic acid according to claim 24, wherein said

polynucleic acid is capable of acting as a primer for specific amplification of a HCV subtype 3c nucleic acid sequence.

35. (new) An isolated HCV polynucleic acid according to claim 25, wherein said polynucleic acid is capable of acting as a primer for specific amplification of a HCV subtype 3c nucleic acid sequence.

36. (new) An isolated HCV polynucleic acid according to claim 24, wherein said polynucleic acid is capable of acting as a probe for specific hybridisation to a HCV type or subtype-specific hybridisation.

37. (new) An isolated HCV polynucleic acid according to claim 25, wherein said polynucleic acid is capable of acting as a probe for specific hybridisation to a HCV type or subtype-specific hybridisation

38. (new) An isolated HCV polynucleic acid according to claim 24, wherein said polynucleic acid is capable of acting as a probe for specific hybridisation to a HCV subtype 3c nucleic acid sequence.

39. (new) An isolated HCV polynucleic acid according to claim 25, wherein said polynucleic acid is capable of acting as a probe for specific hybridisation to a HCV subtype 3c nucleic acid sequence.

40. (new) A kit for determining the presence of HCV genotypes comprising a container and a polynucleic acid sequence according to claim 24.

41. (new) A kit for determining the presence of HCV genotypes comprising a container and a polynucleic acid sequence according to claim 25.

42. (new) A kit for determining the presence of HCV genotypes comprising a container and a primer according to claim 32.

43. (new) A kit for determining the presence of HCV genotypes comprising a container and a primer according to claim 33.

44. (new) A kit for determining the presence of HCV genotypes comprising a container and a primer according to claim 34.

45. (new) A kit for determining the presence of HCV genotypes comprising a container and a primer according to claim 35.

46. (new) A kit for determining the presence of HCV genotypes comprising a container and a probe according to claim 36.

47. (new) A kit for determining the presence of HCV genotypes comprising a container and a probe according to claim 37.

48. (new) A kit for determining the presence of HCV genotypes comprising a container and a probe according to claim 38.

49. (new) A kit for determining the presence of HCV genotypes comprising a container and a probe according to claim 39.

50. (new) A kit for determining the presence of HCV genotypes present in a biological sample comprising the steps of:

- (i) providing a sample nucleic acid,
- (ii) amplifying the nucleic acid with at least one primer according to claim 32,
- (iii) detecting the amplified nucleic acids,
- (iv) inferring the presence of one or more genotypes of HCV present from the observed pattern of amplified fragments.

51. (new) A kit for determining the presence of HCV genotypes present in a

biological sample comprising the steps of:

- (i) providing a sample nucleic acid,
- (ii) amplifying the nucleic acid with at least one primer according to claim 33,
- (iii) detecting the amplified nucleic acids,
- (iv) inferring the presence of one or more genotypes of HCV present from the observed pattern of amplified fragments.

52. (new) A kit for determining the presence of HCV genotypes present in a biological sample comprising the steps of:

- (i) providing a sample nucleic acid,
- (ii) amplifying the nucleic acid with at least one primer according to claim 34,
- (iii) detecting the amplified nucleic acids,
- (iv) inferring the presence of one or more genotypes of HCV present from the observed pattern of amplified fragments.

53. (new) A kit for determining the presence of HCV genotypes present in a biological sample comprising the steps of:

- (i) providing a sample nucleic acid,
- (ii) amplifying the nucleic acid with at least one primer according to claim 35,
- (iii) detecting the amplified nucleic acids,
- (iv) inferring the presence of one or more genotypes of HCV present from the observed pattern of amplified fragments.

54. (new) A kit for determining the presence of HCV genotypes present in a biological sample comprising the steps of:

- (ii) providing a sample nucleic acid,
- (iii) possibly amplifying the nucleic acid with at least one primer,
- (iv) hybridizing the nucleic acids of the biological sample at appropriate conditions with one or more probes according to claim 36, with said probes being possibly attached to a solid substrate,
- (v) possibly washing at appropriate conditions,

- (vi) detecting the hybrids formed,
- (vii) inferring the presence of one or more genotypes of HCV present from the observed hybridization pattern.

55. (new) A kit for determining the presence of HCV genotypes present in a biological sample comprising the steps of:

- (ii) providing a sample nucleic acid,
- (iii) possibly amplifying the nucleic acid with at least one primer,
- (iv) hybridizing the nucleic acids of the biological sample at appropriate conditions with one or more probes according to claim 37, with said probes being possibly attached to a solid substrate,
- (v) possibly washing at appropriate conditions,
- (vi) detecting the hybrids formed,
- (vii) inferring the presence of one or more genotypes of HCV present from the observed hybridization pattern.

56. (new) A kit for determining the presence of HCV genotypes present in a biological sample comprising the steps of:

- (ii) providing a sample nucleic acid,
- (iii) possibly amplifying the nucleic acid with at least one primer,
- (iv) hybridizing the nucleic acids of the biological sample at appropriate conditions with one or more probes according to claim 38, with said probes being possibly attached to a solid substrate,
- (v) possibly washing at appropriate conditions,
- (vi) detecting the hybrids formed,
- (vii) inferring the presence of one or more genotypes of HCV present from the observed hybridization pattern.

57. (new) A kit for determining the presence of HCV genotypes present in a biological sample comprising the steps of:

- (ii) providing a sample nucleic acid,

- (iii) possibly amplifying the nucleic acid with at least one primer,
- (iv) hybridizing the nucleic acids of the biological sample at appropriate conditions with one or more probes according to claim 39, with said probes being possibly attached to a solid substrate,
- (v) possibly washing at appropriate conditions,
- (vi) detecting the hybrids formed,
- (vii) inferring the presence of one or more genotypes of HCV present from the observed hybridization pattern. --

### **REMARKS**

Claims 1-23 have been canceled without prejudice. New claims 24-57 have been added and are pending. No new matter has been added.

Return of an initialed and dated copies of the attached PTO-1449 Form, pursuant to MPEP 609 is requested.

Attached is a Request that the computer readable copy of this Sequence Listing from the grand-parent Patent Application No. 08/362,455, be used for the present application.

The attached paper copy of the Sequence Listing (submitted as part of the application) is the same as the computer-readable and paper copies of the Sequence Listing filed in the grand-parent Application No. 08/362,455. No new matter has been added.

Early and favorable Action on the merits is requested.



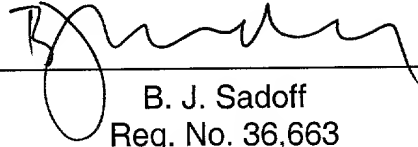
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Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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